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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,872	11/12/1999	KENT C. COCHRUM	49239.5	9965

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/438,872	Cochrum et al.
Examiner	**Art Unit**
Sandra Saucier	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *8/3/01 and 9/26/01*

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3, 9, 11-24, 26, 28-37, 40-42, and 45-63* is/are pending in the applica

4a) Of the above, claim(s) *14-24, 26, 28-37, 40, 42, and 45-63* is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3, 9, 11-13, and 41* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☒ Interview Summary (PTO-413) Paper No(s). 9

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claims 1, 3, 9, 11-24, 26, 28-37, 40-42, 45-63 are pending. Claims 1, 3, 9, 11-13 and 41 are considered on the merits. Claims 14-24, 26, 28-37, 40, 42, 45-63 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 14-24, 26, 28-37, 40 and 42 were withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed without argument in Paper No. 7.

Applicants now present a new argument that the claims involve a combination subcombination situation without specifically delineating what the alleged subcombinations and combinations are. Merely because an admittedly old subcombination, i.e. cross-linked dextran, is incorporated into different articles (combinations) does not mean that the articles or combinations are not restrictable. Please note that there was no common generic claim to the subcombination and the articles now claimed are not combination and subcombination, but merely different and distinct combinations incorporating cross-linked dextran. Thus, this argument is unpersuasive and incorrect because no subcombination was claimed, and therefore, it necessarily follows that no restriction between a subcombination and combination could have been made. Please review MPEP 806.05 regarding combination/subcombination claim construction and restriction practice.

This application contains claims 24, 26, 28-37, 40-42, drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Newly submitted claims 45-58 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The elected invention is drawn to a composition which is a dry, removable wound dressing comprising a matrix containing a hemostatic agent.

Newly presented claims 45-53 and 58 are drawn to a preparation comprising a hemostatic agent, which is crosslinked dextran and a pharmaceutically acceptable carrier. These claims lack the matrix and lack the

modifying elements of being dry and removable. Thus, the new composition does not appear to be the same composition as is under examination.

Newly presented claim 54 is drawn to a composition comprising crosslinked dextran. It lacks the matrix and the modifying elements of being dry and removable. Thus, the new composition does not appear to be the same composition as is under examination.

Newly presented claim 55 is drawn to a foam composition comprising crosslinked dextran. It lacks the matrix and the modifying elements of being dry and removable. Thus, the new composition does not appear to be the same composition as is under examination.

Newly presented claims 56 and 57 are drawn to a composition comprising crosslinked dextran. It lacks the matrix and the modifying elements of being dry and removable. Thus, the new composition does not appear to be the same composition as is under examination.

Newly presented claims 59-63 are drawn to a method. The method does not require a dry, removable wound dressing which is the elected invention. As the elected invention is drawn to a composition which is a dry, removable wound dressing comprising a matrix containing a hemostatic agent, these inventions are deemed to be distinct.

The newly presented claims are considered to be drawn to distinct inventions because of the reasons above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, newly presented claims 45-63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Interference

Applicants have requested a declaration of interference under 35 C.F.R. § 1.607. However, the claims under examination in the present application are composition claims and the claims in the issued patent, US 6060461 sought have declared as interfering are method claims. Thus, no possible interference can be initiated over the issued claims of US 6060461.

Specification

Applicants state that the Swedish Patent cited in the specification is directed to non-critical subject matter and does not need to be incorporated into the specification.

Applicants further state that the cross-linked dextran, now a component of the claims, is an old composition, that is, it is known in the art. The many references to a novel polymer in the specification is now argued to be related to the use of the polymer. Although, this argument seems a bit disingenuous, see for example, the statement on page 24, last paragraph of the specification, where applicants have stated that "the hemostatic polymer composition which is the essence of the novelty upon which patentablility is here predicated may be applied to the wound in the various ways per se known in the art.", it is agreed that cross-linked dextran is indeed known in the art.

On page 21, second paragraph, the newly entered amendment misspells "saccharose".

On page 21, third paragraph, in the newly entered amendment, dichlorohydrin continues to be misspelled.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1,3, 9, 11-13 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "beads or grains of crosslinked dextran". Please explain the difference between beads and grains. If the are the same, they are redundant.

Claim 3 recites that the dressing further comprises a substrate. It is unclear what a substrate is and how the substrate is related to the zone, the matrix and/or the hemostatic agent. Please bear in mind that this is an article which is being described. A claim to an article should describe how the pieces of the article are related to one another.

Claim Rejections - 35 USC § 102

Claims 1, 3, 9, 12 and 13 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by G.B. 1454055 [N].

G.B. 1454055 discloses a wound dressing comprising dextran-epichlorohydrin polymer particles or beads and a matrix which may be paper, cotton fabric, inert plastics, etc. (page 6). Disinfectants may be added to the carrier (page 6, l. 36). Sterilization may be by gamma irradiation (p. 6, l. 130).

Claim Rejections - 35 USC § 103

Claim 11 remains rejected under 35 U.S.C. 103(a) as being unpatentable over G.B. 1454055 [N] as applied to claims 1, 3, 9,12 and 13 above, and further in view of Larson [R] or Eloy *et al.* [S] and US 5196190 [B].

The claim is directed to a dry, stable, sterile wound dressing comprising a matrix containing a hemostatic polymer such as cross-linked dextran and collagen or thrombin or fibrinogen.

Collagen, fibrinogen or thrombin are known hemostatic agents as describe by Larson [R] or Eloy *et al.* [S]

US 5196190 teaches that cross-linked dextran has hemostatic properties (col. 10, l. 50).

The addition of thrombin or fibrinogen or collagen to the wound dressing of G.B. 1454055 would have been obvious when the reference was taken with Larson or Eloy *et al.* and US 5196190 because cross-linked dextran, thrombin, fibrinogen and collagen are known hemostatic agents and have been used in the past as such.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

The references are relied upon as explained below.

Claim 41 remains rejected under 35 U.S.C. 103(a) as being unpatentable over G.B. 1454055 [N] as applied to claims 1, 3, 9, 10, 12 and 13 above, and further in view of US 4549653 [C].

The claims are further directed to the composition of claim 1 which is a dry, sterile, stable wound covering comprising a matrix containing a polymer made by reacting an uncharged organic compound with hydroxyl groups (dextran) with a bifunctional compound (epichlorohydrin) further incorporating a flexible substrate sheet and a protective layer enclosing it.

US 4549653 discloses a strip used as a wound covering comprising a flexible substrate sheet carrying a dry sterile wound dressing and a protective covering.

The enclosure of the flexible, sterile wound covering of G.B. 1454055 or US 4703336 in the enclosure of US 4549653 would have been obvious because it is well known in the art to form enclosures for wound dressings to maintain cleanliness.

One of skill in the art would have been motivated at the time of invention to make these substitutions or additions in order to obtain the resulting composition or article as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicants argue that '055 uses a dextran-epichlorohydrin polymer that excludes 50-270 KDa proteins such that fibrinogen and its degradation products are partly or completely excluded. Please note that the composition claims under examination do not have any size exclusion requirements for the cross-linked dextran beads, but merely recited a desired result. Applicants argue that their desired result would not flow from the use of the prior art dressing because the prior art bead excludes fibrinogen, while their bead concentrates fibrinogen on the surface of the bead. This appears to be essentially the same function as in the prior art disclosure. On page 20 of the instant specification, it is explained that fibrinogen is excluded from the interior of the bead (just outside the first layer) and that fibrinogen has a mw of about 340,000 Da. As the prior art bead has an exclusion range of 270,000 to 50,000 Da, fibrinogen would be excluded from the interior of the prior art bead in a similar fashion. As the prior art bead is

composed of the same material as the instant bead, has about the same exclusion properties and size, it is reasonably assumed to function in the same manner.

In spite of applicant's arguments to substantiate the claimed article as novel or unobvious, insofar as the limitations of the article rely on elements that instead of being characterized by technical features suitable for the identification of an article, are imprecisely defined by means of functional features which merely recite the desired result to be achieved, the subject matter is still considered to be anticipated or obvious over the disclosures of the prior art.

Please note that the claims under examination are composition claims, not method claims and arguments directed to the intended use of a composition or limitations directed to the intended use of a composition, are of little patentable weight.

Conclusion

This application contains claims drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

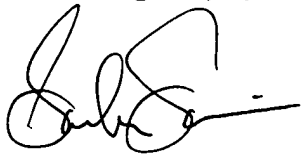
Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work

schedule for Examiner Saucier is 8:30AM to 6:00PM Tuesday-Friday and every other Monday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of papers is (703) 308-2742 or (703) 305-3592.



Sandra Saucier
Primary Examiner
Art Unit 1651
December 10, 2001